

5

BIFURCATED AXIALLY FLEXIBLE STENT

Cross Reference

10 This application is a continuation-in-part of Serial
No. 09/028,383, filed February 24, 1998 which is a
continuation-in-part and claims priority from U.S.
Application Serial No. 08/934,974, filed September 22,
1997. Serial No. 08/934,974 claims priority from U.S.
Application Serial No. 60/010,686, filed January 26, 1996,
15 now abandoned; and U.S. Application Serial No. 60/017,479,
filed April 26, 1996, now abandoned; and U.S. Application
Serial No. 60/017,415 filed May 8, 1996; and U.S.
Application Serial No. 60/024,110, filed August 16, 1996;
and U.S. Application Serial No. 08/770,236, filed December
20 20, 1996, all such patent applications of which are
incorporated herein by reference.

Field of the Invention

25 Generally, this invention relates to balloon
catheters. More specifically, this invention relates to
balloon catheters used for stent delivery. Most
specifically, this invention relates to balloon catheters
useful for delivering bifurcated stents. In particular,
30 this invention relates to balloon catheters, which deliver
stents to an arterial bifurcation.

5 Background of the Invention

10 A stent is commonly used as a tubular structure left
inside the lumen of a duct to relieve an obstruction.
Commonly, stents are inserted into the lumen in a non
expanded form and are then expanded autonomously (or with
the aid of a second device *in situ*. A typical method of
expansion occurs through the use of a catheter mounted
angioplasty balloon which is inflated within the stenosed
vessel or body passageway in order to shear and disrupt
15 the obstructions associated with the wall components of
the vessel and to obtain an enlarged lumen.

20 In the absence of a stent, restenosis may occur as a
result of elastic recoil of the stenotic lesion. Although
a number of stent designs have been reported, these
designs have suffered from a number of limitations. These
include restrictions on the dimension of the stent such as
describes a stent which has rigid ends (8mm) and a
flexible median part of 7-21mm. This device is formed of
multiple parts and is not continuously flexible along the
25 longitudinal axis. Other stent designs with rigid
segments and flexible segments have also been described.

30 Other stents are described as longitudinally flexible
but consist of a plurality of cylindrical elements
connected by flexible members. This design has at least
one important disadvantage, for example, according to this
design, protruding edges occur when the stent is flexed
around a curve raising the possibility of inadvertent

5 retention of the stent on plaque deposited on arterial walls. This may cause the stent to embolize or move out of position and further cause damage to the interior lining of healthy vessels. (See Figure 1(a) below).

10 Thus, stents known in the art, which may be expanded by balloon angioplasty, generally compromise axial flexibility to permit expansion and provide overall structural integrity.

15 Catheter balloons and medical devices incorporating them are well known for use in the surgical arena. For instance, during angioplasty, stenoses and/or obstructions in blood vessels and other body passageways are altered, in order to increase blood flow through the obstructed area of the blood vessel. For example, in a typical
20 balloon angioplasty procedure, a partially occluded lumen is enlarged through the use of a balloon catheter that is passed percutaneously by way of the arterial system by way to the site of the vascular obstruction. The balloon is
25 then deflated to dilate the vessel lumen at the site of the obstruction.

30 Furthermore, another typical procedure uses a "scaffolding," or stent placed on the balloon angioplasty catheter for similar delivery through the arterial system to the site of a vascular obstruction. Thereafter, the balloon angioplasty catheter is inflated, thereby expanding the stent placed on the catheter. When the stent expands, it similarly expands the lumen so that

5 after removal of the deflated catheter, the stent is retained in its expanded position and thereby holds open that formerly obstructed area of the body passageway.

10 Essentially, a balloon catheter is a thin, flexible length of tubing having a small inflatable balloon at a desired location along its length such as at or near its tip. Balloon catheters are designed to be inserted into a body passageway such as the lumen of a blood vessel, a passageway in the heart, a urological passageway, and the like. Typically, the passage of the balloon catheter into 15 the body passageway is done with guidance, such as x-ray or fluoroscopic guidance.

20 In practice, stent delivery is quite complex. That is, a stent is sometimes required to be placed in a rather tortuous area of the vasculature. In this instance, it is often necessary to have a catheter which is capable of negotiating tight turns, and/or being placed along a bifurcated length of blood vessel. In some instances, 25 while a generally occluded section of blood vessel can readily be stented, it is often difficult to place a second stent at the other portion of a bifurcation. In other words, one can imagine the bifurcation as an inverted letter "Y" within the body. (The approach of the catheter concerning this inverted "Y" shape is generally 30 through one of the legs in the "Y".) Therefore, the balloon passes both between the leg and the trunk or base of the "Y" rather readily. However, once a stent is placed along these two legs, it is rather difficult to

5 place a second stent at or near the junction of the first
leg and the base of the letter "Y". Of course, the same
can hold true when the approach is via the base of the "Y"
and delivery of the first stent is to one of the legs.
This is all the more true because as one advances through
10 the vasculature, the arterial sizes go from quite large
(greater than 1cm diameter) to rather small (some time
less than 2.5 mm diameter).

15 It would be desirable, therefore, to create a system
which allows for delivery of a single stent or pair of
stents at a bifurcation in the vasculature. It would
further be desirable for this stent or for this delivery
system to be able to negotiate the bends of the
bifurcation, and moreover, to provide for easy access when
20 one stent is already placed. Furthermore, it would be
quite useful in order to be able to apply the second
stent, for the first stent to be reliably placed every
time so that the user knows exactly where the bifurcation
is located, and as well where the stent must be
25 appropriately oriented in order to readily access the
second leg of the "Y" of the bifurcation.

30 Finally, it would be useful for a device such as a
desired delivery system to carry a stent capable of
allowing secondary access to a bifurcated portion of the
vasculature. Thus, it would be most desirable for the
device to comprise a catheter capable of balloon delivery
of a stent at a bifurcation, and also balloon delivery of
a second stent at the bifurcation.

5 Summary of the Invention

10 The present invention overcomes some perceived shortcomings of prior art stents by providing a stent with axial flexibility. In a preferred embodiment, the stent has a first end and a second end with an intermediate section between the two ends. The stent further has a longitudinal axis and comprises a plurality of longitudinally disposed bands, wherein each band defines a generally continuous wave along a line segment parallel to the longitudinal axis. A plurality of links maintains the bands in a tubular structure. In a further embodiment of the invention, each longitudinally disposed band of the stent is connected, at a plurality of periodic locations, by a short circumferential link to an adjacent band. The wave associated with each of the bands has approximately the same fundamental spatial frequency in the intermediate section, and the bands are so disposed that the waves associated with them are spatially aligned so as to be generally in phase with one another. The spatially aligned bands are connected, at a plurality of periodic locations, by a short circumferential link to an adjacent band.

30 In particular, at each one of a first group of common axial positions, there is a circumferential link between each of a first set of adjacent pairs of bands.

At each one of a second group of common axial positions, there is a circumferential link between each of

5 a second set of adjacent rows of bands, wherein, along the
longitudinal axis, a common axial position occurs
alternately in the first group and in the second group,
and the first and second sets are selected so that a given
band is linked to a neighboring band at only one of the
10 first and second groups of common axial positions.

In a preferred embodiment of the invention, the
spatial frequency of the wave associated with each of the
bands is decreased in a first end region lying proximate
15 to the first end and in a second end region lying
proximate to the second end, in comparison to the spatial
frequency of the wave in the intermediate section. In a
further embodiment of the invention, the spatial frequency
of the bands in the first and second end regions is
20 decreased by 20% compared with the spatial frequency of
the bands in the intermediate section. The first end
region may be located between the first end and a set of
circumferential links lying closest to the first end and
the second end region lies between the second end and a
25 set of circumferential links lying closest to the second
end. The widths of corresponding sections of the bands in
these end regions, measured in a circumferential
direction, are greater in the first and second end regions
than in the intermediate section. Each band includes a
30 terminus at each of the first and second ends and the
adjacent pairs of bands are joined at their termini to
form a closed loop.

5 In a further embodiment of the invention, a stent is
provided that has first and second ends with an
intermediate section therebetween, the stent further
having a longitudinal axis and providing axial
flexibility. This stent includes a plurality of
10 longitudinally disposed bands, wherein each band defines a
generally continuous wave having a spatial frequency along
a line segment parallel to the longitudinal axis, the
spatial frequency of the wave associated with each of the
bands being decreased in a first end region lying
15 proximate to the first end and in a second end region
lying proximate to the second end, in comparison to the
spatial frequency of the wave in the intermediate section;
and a plurality of links for maintaining the bands in a
tubular structure. The first and second regions have been
20 further defined as the region that lies between the first
and second ends and a set of circumferential links lying
closest to the first end and second end.

25 In a further embodiment the widths of the sectionals
of the bands, measured in a circumferential direction, are
greater in the first and second end regions than in the
intermediate section.

30 In yet an additional embodiment, the stent is divided
into a group of segments, and each of the segments are
connected by a flexible connector. In addition, the stent
segments are provided with enhanced flexibility at the
flexible connectors, due to the geometrical configuration
of the flexible connectors.

5 Furthermore, the current stent can be modified to
provide for bifurcated access, whereas the stent itself is
uniform throughout. If the manufacturer designs such a
stent to have an essential opening, then it is possible to
10 place the stent such that a pair of stents can be placed
one through the other. In this fashion, the stents are
capable of being placed at a bifurcation, without any
welding or any special attachments. The interlocking
mechanism can be incorporated into the stent design to
15 cause the stent to interlock at the desired position
during assembly of the device.

20 In practice, therefore, the current catheter device
consists of a balloon catheter which comprises a shaft
portion having a proximal and a distal end. The shaft
portion has a guidewire lumen therethrough. The lumen has
a proximal opening and a distal opening. The distal
opening of the shaft portion is located at the distal end
of the shaft. A balloon is connected to the shaft at the
shaft distal end. The balloon has proximal and distal
25 ends and a first guidewire lumen through it. The balloon
guidewire is in fluid communication with the guidewire
lumen of the shaft and the first balloon guidewire lumen
also has proximal and distal ends. The balloon has a
second guidewire lumen, the second guidewire lumen
30 containing a distal opening located proximal to the distal
opening of the first guidewire lumen.

Further, there is disclosed a method of stent
placement which comprises first guiding a guidewire

5 through the vasculature. Second, a balloon catheter which
contains two guidewire lumens is strung along the
guidewire into position at the bifurcation. The distal
opening of the second guidewire lumen abuts the proximal
10 strung through the first balloon catheter and out the
distal opening of the second guidewire lumen. Thus,
resident in the second bifurcation leg is the second
guidewire. Then, a second standard stent delivery balloon
catheter is guided along the second guidewire to a
15 position within the bifurcation. Typically, expansion of
both stents can be done one right after the other after
proper placement of the first and second balloons.

Brief Description of the Drawings

20 The foregoing aspects of the invention will be more
readily understood by reference to the following detailed
description, taken with the accompanying drawings, in
which:

25 Figures 1(a) and 1(b) are side views of a stent
having circumferentially disposed bands wherein the stent
is in axially unbent and bent positions respectively, the
latter showing protruding edges;

30 Figures 1(c) and 1(d) are side views of an axially
flexible stent in accordance with the present invention
wherein the stent is in unbent and bent positions

5 respectively, the latter displaying an absence of
protruding edges;

10 Figure 2 is a side view of a portion of the stent of
Figures 1(c) and 1(d) showing the longitudinal bands,
spaces, and inner radial measurements of bends in the
bands being measured in inches;

15 Figures 3(a) and 3(b) show a portion of the stent of
Figure 2 with two bands between two circumferential links
(a) before expansion in the unexpanded state; and (b)
after expansion, in the deformed state;

20 Figure 4 is a view along the length of a piece of
cylindrical stent (ends not shown) prior to expansion
showing the exterior surface of the cylinder of the stent
and the characteristic banding pattern;

25 Figure 5 is an isometric view of a deflection plot
where the stent of Figure 2 is expanded to a larger
diameter of 5mm;

30 Figure 6 shows a two-dimensional layout of the stent
of Figure 4 to form a cylinder such that edge "A" meets
edge "B", and illustrating the spring-like action provided
in circumferential and longitudinal directions;

Figure 7 shows a two dimensional layout of the stent.
The ends are modified such that the length (L_A) is about

5 20% shorter than length (L_B) and the width of the band A is
greater than the width of band B;

10 Figure 8 shows a perspective view of a stent
containing flexible connectors as described in the present
invention;

15 Figure 9 shows a stent in which the flexible
connectors are attached to stent segments, in layout form.
These flexible connectors are attached in an every-other-
segment pattern;

20 Figure 10 shows a layout view where the stent
segments are connected with a flexible connector in every
stent segment pattern;

25 Figure 11 shows a schematic of the unexpanded stents
when loaded on the stent delivery system;

Figure 12 shows the stents placed alone;

30 Figure 13 shows the stents as expanded without the
delivery system;

Figure 14 shows a modification of the stent in a
layout view;

Figure 15 is a plan view of the balloon of the
present system;

5 Figure 16 is an assembly view of the same balloon;

Figure 17 is a view of the balloon when in use;

10 Figure 18 is a assembly view of another stent which
may be used on the balloons of Figures 15-17; and

Figure 19 is a plan view of the stent of the previous
figure.

15 Detailed Description of Specific Embodiments

20 Improvements afforded by embodiments of the present
invention include (a) increased flexibility in two planes
of the non-expanded stent while maintaining radial
strength and a high percentage open area after expansion;
(b) even pressure on the expanding stent that ensures the
consistent and continuous contact of expanded stent
against artery wall; (c) avoidance of protruding parts
during bending; (d) removal of existing restrictions on
25 maximum of stent; and reduction of any shortening effect
during expansion of the stent.

30 In a preferred embodiment of the invention, an
expandable cylindrical stent 10 is provided having a
fenestrated structure for placement in a blood vessel,
duct or lumen to hold the vessel, duct or lumen open, more
particularly for protecting a segment of artery from
restenosis after angioplasty. The stent 10 may be
expanded circumferentially and maintained in an expanded

5 configuration, that is circumferentially rigid. The stent
10 10 is axially flexible and when flexed at a bend, the
stent 10 avoids any externally protruding component parts.

10 Figure 1 shows what happens to a stent 10, of a
similar design to a preferred embodiment herein but
utilizing instead a series of circumferentially disposed
bands, when caused to bend in a manner that is likely
15 encountered within a lumen of the body. A stent 10 with a
circumferential arrangement of bands (1) experiences an
effect analogous to a series of railroad cars on a track.
As the row of railroad cars proceeds around the bend, the
corner of each car proceeding around the bend after the
coupling is caused to protrude from the contour of the
20 track. Similarly, the serpentine circumferential bands
have protrusions (2) above the surface of the stent 10 as
the stent 10 bends.

25 The embodiment shown in Figures 1(c) and 1(d) and
Figure 7 has bands (3) which are axially flexible and are
arranged along the longitudinal axis. This allows the
stent to bend so that the bent bands (4) do not protrude
from the profile of the curve of the stent 10.
Furthermore, any flaring at the ends of the stent 10 that
might occur with a stent 10 having a uniform structure is
30 substantially eliminated by introducing a modification at
the ends of the stent 10. This modification comprises
decreasing the spatial frequency and increasing the width
of the corresponding bands in a circumferential direction

5 (L_A and A) compared to that of the intermediate section.
(l_B and B).

10 In an embodiment of the invention, the spatial
frequency L_A may be decreased 0-50% with respect to L_B, and
the width A may be increased in the range of 0-150% with
respect to B. Other modifications at the ends of the
stent 10 may include increasing the thickness of the wall
of the stent 10 and selective electropolishing. These
modifications protect the artery and any plaque from
15 abrasion that may be caused by the stent 10 ends during
insertion of the stent 10. The modification also may
provide increased radio-opacity at the ends of the stent
10. Hence it may be possible to more accurately locate
the stent 10 once it is in place in the body.

20 The embodiment as shown in Figures 2 and 6 has the
unique advantage of possessing effective "springs" in both
circumferential and longitudinal directions shown as items
(5) and (6) respectively. These springs provide the stent
25 10 with the flexibility necessary both to navigate vessels
in the body with reduced friction and to expand at the
selected site in a manner that provides the final
necessary expanded dimensions without undue force while
retaining structural resilience of the expanded structure.

30 As shown in both Figures 2, 4 and 6, each
longitudinal band undulates through approximately two
cycles before there is formed a circumferential link to an
adjacent band. Prior to expansion, the wave W associated

5 with each of the bands may have approximately the same
fundamental spatial frequency, and the bands are so
disposed that the wave W associated with them are
spatially aligned, so as to be generally in phase with one
another as shown in Figure 6.

10 The aligned bands on the longitudinal axis are
connected at a plurality of periodic locations, by a short
circumferential link to an adjacent band. Consider a
first common axial position such as shown by the line X-X
15 in Figures 4 and 6. Here an adjacent pair of bands is
joined by circumferential link 7. Similarly other pairs
of bands are also linked at this common axial position.
At a second common axial position, shown in Figure 6 by
the line Y-Y, an adjacent pair of bands is joined by
20 circumferential link 8. However, any given pair of bands
that is linked at X-X is not linked at Y-Y and vice-versa.
The X-X pattern of linkages repeats at the common axial
position Z-Z. In general, there are thus two groups of
common axial positions. In each of the axial positions of
25 any one group are links between the same pairs of adjacent
bands, and the groups alternate along the longitudinal
axis of the embodiment. In this way, circumferential
spring 6 and the longitudinal spring 6 are provided.

30 A feature of the expansion event is that the pattern
of open space in the stent 10 of the embodiment of Figure
2 before expansion is different from the pattern of the
stent 10 after expansion. In particular, in a preferred
embodiment, the pattern of open space on the stent 10

5 before expansion is serpentine, whereas after expansion,
the pattern approaches a diamond shape (3a, 3b). In
embodiments of the invention, expansion may be achieved
using pressure from an expanding balloon or by other
mechanical means.

10 In the course of expansion, as shown in Figure 3, the
wave W shaped bands tend to become straighter. When the
bands become straighter, they become stiffer and thereby
withstand relatively high radial forces. Figure 3 shows
15 how radial expansion of the stent 10 causes the
fenestrations to open up into a diamond shape with maximum
stress being expended on the apices of the diamond along
the longitudinal axis. When finite element analyses
including strain studies were performed on the stent 10,
20 it was found that maximum strain was experienced on the
bands and links and was below the maximum identified as
necessary to maintain structural integrity.

25 The optimization of strain of the stent 10 is
achieved by creating as large a turn radius as possible in
the wave W associated with each band in the non-expanded
stent 10. This is accomplished while preserving a
sufficient number of bands and links to preserve the
structural integrity of the stent 10 after expansion. In
30 an embodiment of the invention, the strain may be less
than 0.57 inches/inch for 316L stainless steel. The
expansion pressure may be 1.0-7.0 atmospheres. The number
of bands and the spatial frequency of the wave W on the
longitudinal axis also affect the number of

circumferential links. The circumferential links contribute structural integrity during application of radial force used in expansion of the stent 10 and in the maintenance of the expanded form. While not being limited to a single set of parameters, examples of a stent 10 of the invention having a longitudinal axis and providing axial flexibility of the type shown in Figure 6, may include the following: stents 10 having an expanded diameter of 4mm and a length of 30mm that for example may have about 8-12 rows, more particularly 10 rows; about 6-10 slots, more particularly 8 slots (a slot is shown in Figure 6 as extending between X and Z); and a wave W amplitude of about 1/4-1/10 of a slot length, more particularly 1/8 of a slot length.

The stents described may be fabricated from many methods. For example, the stents may be fabricated from a hollow or formed stainless steel tube that may be cut out using lasers, electric discharge milling (EDM), chemical etching or other means. The stents are inserted into the body and placed at the desired site in an unexpanded form. In a preferred embodiment, expansion of the stent is effected in a blood vessel by means of a balloon catheter, where the final diameter of the stent is a function of the diameter of the balloon catheter used.

In contrast to stents of the prior art, the stent of the invention can be made at any desired length, most preferably at a nominal 30mm length that can be extended or diminished by increments, for example 1.9mm increments.

5

10

15

20

25

30

It will be appreciated that a stent in accordance with the present invention may be embodied in a shape memory material, including, for example, an appropriate alloy of nickel and titanium; or stainless steel. In this embodiment after the stent has been formed, it may be compressed so as to occupy a space sufficiently small as to permit its insertion in a blood vessel or other tissue by insertion means, wherein the insertion means include a suitable catheter, or flexible rod. On emerging from the catheter, the stent may be configured to expand into the desired configuration where the expansion is automatic or triggered by a change in pressure, temperature or electrical stimulation.

An embodiment of the improved stent has utility not only within blood vessels as described above but also in any tubular system of the body such as the bile ducts, the urinary system, the digestive tube, and the tubes of the reproductive system in both men and women.

In yet a further embodiment, there is described a stent 10 as presently disclosed containing a multiplicity of curvilinear segments 20. These curvilinear segments 20 are connected to each other via a generally perpendicular connector 25. The generally perpendicular connector 25 lies substantially in the plane perpendicular to the longitudinal axis of the stent 10. Each of the stent 10 segments as described herein is connected to an adjacent stent 10 segment. This is done using a series of flexible

5 connectors. Importantly, the connectors themselves can be
made narrower at their midpoints. This enhances the
possibility of flexure at that point. Of course, it is to
be realized that alternate designs of the connector to
insure flexibility are possible, and contemplated by this
10 invention.

In essence therefore, the stent 10 as described in
Figure 8 is a stent 10 of considerable flexibility when
compared to more rigid rectilinear stents. Nonetheless,
15 the stent 10 of the present invention does not depart from
the basic concepts set forth herein, in that it discloses
a continuously curvilinear strut. This curvilinear strut
is connected to other curvilinear struts via a series of
"second" more flexible connectors, described above.
20

In any regard, it can be seen that the stent 10 of
the present invention incorporates various new and useful
members. One of them is the flexible connector in
conjunction with a generally curvilinear stent. Another
25 is the use of the generally larger struts at the ends of
the stent 10 in order to provide for continued support at
the stent 10 ends. A final aspect is the use of flexible
connectors amongst stent 10 segments to provide for
greater flexibility.
30

In all regards, however, it is to be seen that the
present invention is to be determined from the attached
claims and their equivalents.

5 As can be seen from Figures 11 through 14, an
improved device 100 of the present invention can also be
made to perform in a bifurcated fashion. In this way, the
stent 101 contains a central opening 102. This central
10 opening 102 allows for the passage of an unexpanded stent
103 of the same size. Typically of course, the two stents
101,103 will have the same general configuration, and one
can pass through the other on the same type of diameter
balloon. In fact, the balloon 150 as seen in the current
15 figures 11-16 is a bifurcated balloon, but need not be.
Two separate balloons are certainly capable of performing
the same function. The balloons are preferably less than
6 Fr in their unexpanded shape in a preferred embodiment,
but of course, need not be so constrained.

20 As seen in figures 11-14, the first stent 101 (the
lower one in the figure) is loaded on one of the balloons
151. It has an opening 102 central to it. This opening
faces the upper stent 103 and balloon 152, the upper stent
102 loaded on the second balloon 152. The upper stent
25 103, when loaded on the second balloon 152 also has an
opening 104 which faces the lower stent 101. In this
fashion, as the second stent 103 is strung through the
first stent 101, it is placed in such a fashion so as to
have a mutually facing contact with the first stent 101.
30 Then, as the balloon and stent combination is guided
through the human anatomy, the devices will go toward a
bifurcation. When this happens, the device is caused to
split using various guide wire techniques. Then, each of
the respective balloons is inflated.

5

10

On this inflation, the entire device is expanded such as seen in Figure 13. Thus, the entire bifurcation is covered, and yet in a much easier than typical bifurcated expansions. What is unique is that there is no welding of the stents 101, 103 together, they can be common "off-the-shelf" stents modified only slightly so as to be useful for this particular need.

15

20

25

It should be noted that the stent of Figures 11-14 can be designed with any slot or wire configurations or of any high density materials or composites and can be balloon expandable or self-expanding or even the combination of both. The devices can be sold separately from separate catheters to be assembled during the desired procedure by the clinicians; can be used with a bifurcated balloon or two separate balloons; or incorporated with one or more radio-opaque markers to allow for better positioning in radio-opacity. The bifurcated stent delivery system is placed by crimping over two balloons and then expanded at the sight of the lesion.

30

As seen from Figures 15-17, there is described in this present invention a balloon 510, in which is contained a standard balloon catheter 520. These catheters are described in, for instance, U.S. Patent Nos. 5,108,415; 5,156,612 and 5,304,197. Such patents are owned by a common assignee of the present invention, and incorporated herein by reference. Uniquely, however, the current balloon 510 contains a side hole 515 in the

5 balloon. The side hole 515 is placed at an exit port 516
in the middle 517 of the balloon 510. This side hole 515
creates access to a lumen 525 created in the side of the
catheter 510. Thus, this side hole 515 creates an access
channel useful for the stent 101 of the current invention.

10 So in use therefore, the catheter 510 is advanced
into the lumen of the artery, as would be typical
angioplasty catheter. First, a guidewire 550 is placed
within lumen 530 of the catheter 510. Second, the
15 catheter 510 is tracked over the guidewire and into the
lumen. Then, the guidewire 550, specially formed for this
use is retracted until its tip 555 is placed at the distal
marker 535 of the current catheter 516. Then, the
guidewire 550 is rotated so that its tip 555 "pops" out of
20 the side hole 515 created in the side lumen 525 of the
present catheter 510. The guidewire 550 is then advanced
through the side branch artery to give access to the side
branch.

25 In Figures 18-19, the first item described will be
the structure of stent 200 in accordance with the
invention and illustrated in figures 18-19. The stent
200 is an improvement over other bifurcated stent ideas,
in that the stent is continuous through the mid-section
30 250 of the main branch segment 210, 220. Segment 230 is
connected by a weld or other means (such as a pivotable
hook or a ball in socket joint) to another section 220 to
form the "Y"-shaped stent. Such design will allow for

5 greater vessel coverage at the intersection point of the
bifurcation.

10 As was mentioned earlier, stent 200 comprises three
tubular sections (210, 220, and 230) and a continuous
connection (240). Sections 210, 220, 230 have struts
211, 221, 231 of sinusoidal shape. Of course, any known
shape (e.g., straight struts, are possible).

15 The first section (210) is a proximal section
having as its center axis L. It is intended for
insertion into main stem of blood vessel for treatment
upstream of a bifurcation.

20 The first distal section (220) having as its
section axis L' is at least approximately aligned with
proximal section 210 prior to use. This first distal
section 220 is intended for insertion to a blood distal
branching off from the bifurcation from a proximal blood
vessel, into which section 210 is to be placed. The
25 first distal section (220) is attached to proximal
section 210 by some of the omega-shaped connector
members 250 seen in Figures 18 and 19. Omega-shaped
connectors 250, it should be realized, are of different
shape than struts 211, 221; these omega-shaped
30 connectors 250 are formed to maximize flexibility, and
it is to be understood that these struts need not be
limited to the design disclosed here. It is envisioned
that other flexible connections are possible.

5 The second distal section (230) having as its axis
L" is positioned at the side of the first distal section
220, and has the advantage of being parallel to the
latter prior to use. The second distal section 230 is
intended to be inserted into a second distal blood
10 vessel branching off from the bifurcation.

15 The two distal sections 220 and 230 have their
proximal ends linked by the connection member 260, which
is a weld joint comprising elements 261, 262 seen in
Figure 18. Dowel 261 fits into hole 262 to form weld
260.

20 Each of section 210, 220, and 230 is preferably
formed from a tubular component perforated with a
slotted tubular pattern such that the structure of
sections 210, 220, 230 allows them to expand along their
circumferences.

25 In practice section 210, 220, and 230 of stent is
200 can be manufactured from extruded cylindrical parts
made of a bendable metal alloy such as 316L stainless
steel, but may also be made from other known metals such
as nitinol. The external diameter of sections 210, 220,
230 typically ranges from 1mm to 4mm prior to use, and
30 can be expanded further than 2mm and 8mm.

Sections 210, 220 are preferably manufactured from
a single tubular part in which flexible connectors, such
as omega-shaped connectors 250 are formed via machining.

5

Weld points 261, 262 are preferably joined by means of, for example, laser welding, or other acceptable alternatives.

10

Furthermore, proximal end 235 of the second distal section 230 may be tapered at the other side of the connector 250. It extends forward in its peripheral area opposite the omega-shaped connectors 250. This tapered portion may also be determined by a plane that is inclined with reference to L' perpendicular to the plane of symmetry of the stent 200.

15

20

After expansion, when the stent 200 is installed at the a bifurcation of the two vessels, distal portion 215 of the proximal section 210 is fit together with the proximal ends 225, 235, of sections 220, 230 of the stent, and ensures maximum coverage of the dilated bifurcation area. This is especially true since weld 260 holds the relative position of sections 220, 230 and the relative positions of sections 210, 220 is set, and covered by omega-shaped connectors 250.

25

30

In this way, once in place, the whole of the grid of the bifurcated stent 200 covers the proximal and distal portions of the two branching vessels and the whole of the dilated bifurcation area.

The stents themselves can be made from any high density material or composite. These stents can be

5 balloon expandable or self-expanding or a combination of
both. They can be used on catheters as described herein
or on standard catheters.

10 These and other objects of the present invention are
accomplished in a stent delivery system which consists of
an ingeniously modified angioplasty catheter. Typical
angioplasty catheters contain a central lumen useful for
stringing a guidewire therethrough. The guidewire then
15 guides the balloon from a point outside the body, along
its length, to a point which is about to be stented. The
balloon of the angioplasty catheter holds the stent as it
is guided through the vasculature. When the obstruction
is reached, the balloon is inflated, the stent is
similarly inflated, and then the balloon can be deflated.
20 Upon deflation, the balloon can be retracted through the
vasculature along the guidewire.

25 In the present invention, a second guidewire lumen is
placed at least within the balloon. (It should also be
realized that the second guidewire lumen also can readily
be placed along a length of the catheter shaft.) This
second guidewire lumen is useful for attacking the
bifurcated vessel. What occurs, therefore, is the
following: a large stent is placed on the balloon so
30 modified. Thereafter, the guidewire is tracked through
the body to a point past the obstruction, which for the
purposes described herein, is presumed to occur at or near
a bifurcation. Onto the guidewire is tracked the modified
stent delivery system. The balloon guidewire lumen is

5 placed on to the guidewire outside the body and it is then
moved along the guidewire to a point inside the body. The
exit portion of the second balloon guidewire lumen is
somewhere proximal to the distal end of the balloon, so
that the entire balloon can be moved to a position along
10 the vasculature at the obstruction in the body passageway.

When the obstruction is reached, the balloon can be
inflated. This will usually take care of the "base" and
one of the "legs" of the bifurcation. When inflated, a
15 stent which is associated with the stent delivery system
is similarly inflated. This stent has an opening situated
along a portion of its wall. This opening is useful for
opening the second leg of the bifurcated area.

20 The second area is opened in the following manner: a
second balloon angioplasty catheter, this time containing
a single basic stent is placed along the guidewire during
positioning of the balloon catheter. A second guidewire
is then strung through the catheter to a position where it
25 emerges from the second opening. Then, the second
catheter is guided along the second guidewire so that it,
too, is placed along the second guidewire after the
guidewire emerges from the distal opening of the balloon
second guidewire opening. Then, the second catheter can
30 be inflated when it is resident in the second "leg" of the
bifurcation. At that point, because the first leg has
already been expanded and the base of the bifurcation has
been expanded, once the second leg of the bifurcation is

5 expanded, the entire bifurcation has been attended to and
the patient is properly stented.

10 Further, there is disclosed a method of stent
placement which comprises first guiding a guidewire
through the vasculature. Second, a balloon catheter which
contains two guidewire lumens is strung along the
guidewire into position at the bifurcation. The distal
opening of the second guidewire lumen abuts the proximal
end of the bifurcation. Thereafter, a second guidewire is
15 strung through the first balloon catheter and out the
distal opening of the second guidewire lumen. Thus,
resident in the second bifurcation leg is the second
guidewire. Then, a second standard stent delivery balloon
catheter is guided along the second guidewire to a
20 position within the bifurcation. Typically, expansion of
both stents can be done one right after the other after
proper placement of the first and second balloons.